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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,290	08/03/2001	David M. Goldenberg	IMMU:015US	5316

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ROSSI, KIMMS & McDOWELL LLP.
P.O. BOX 826
ASHBURN, VA 20146-0826

EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
04/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/921,290	GOLDENBERG, DAVID M.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-10,14-18,25-29,32-37,41-44,46 and 48-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-10,14-18,25-29,32-37,41-44,46 and 48-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44, 46 and 48-56 are pending.

Claims 1 and 18 have been amended.

Claims 51-56 have been added.

Claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44, 46 and 48-56 are examined on the merits.

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 102

2. The rejection of claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44 and 48-50 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0219203 A1 (effective filing May 10, 1999) are withdrawn in light of Applicant's declaration under 37 CFR §1.132.

3. The rejection of claims 1-3, 5, 8-10, 15-18, 25, 26, 32, 33, 37, 41-43, 46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2001/0018041 A1 (filed April 16, 2001) are withdrawn in light of Applicant's amendments.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2001/0018041 A1 (filed April 16, 2001), and further in view of U.S. Patent Application Publication number 2004/0219203 A1 (effective filing May 10, 1999) is withdrawn in light of the amendment.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5, 8-10, 15-18, 25, 26, 32, 33, 37, 41-43, 46, 48, 54, 55 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2001/0018041 A1 (filed April 16, 2001), as evidenced by the Manual of Molecular and Clinical Laboratory Immunology, 7th edition, (Editors: Detrick et al., 2006). The publication discloses methods of treating humans, as well as dogs, casts, horses, cows, pigs, goats, sheep and ungulates (i.e. llamas and alpacas) having CD40+ malignancies, B-cell lymphomas and leukemias with compositions comprising anti-

CD20 antibodies (including bispecific antibodies), chemotherapeutic agents, immunosuppressive agents, such as prednisone and radiotherapy, see abstract; page 3, sections 0027 and 0033; section 0082 bridging pages 7 and 8; page 8, section 0091; page 9, section 0092; page 10, sections 0104-0106. The therapeutic composition also comprises a combination of two or more naked antibodies against different epitopes and a fusion protein of antibody combinations, see page 3, sections 0018 and 0027; and page 10, section 0104.

Applicants note in the bridging paragraph of pages 6 and 7 of the Remarks "treatment with anti-CD40L antibodies is a necessary feature of the ...regimen disclosed in [instant publication]. Independent claim 1 now includes "*and, optionally, a cytotoxic drug, an immunosuppressive drug, or an immunomodulator, in a pharmaceutically acceptable carrier*". A therapeutic monoclonal antibody is regarded as an immunomodulatory agent, see Whiteside, page 1171, column 1. Hence, the teaching noted by Applicant does not preclude the instant rejection. The instantly claimed method does not exclude the treatment with anti-CD40L antibodies.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44, 46, 48, 50 and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2001/0018041 A1 (filed April 16, 2001), as evidenced by the Manual of Molecular and Clinical Laboratory Immunology, 7th edition, (Editors: Detrick et al., 2006), and further in view of Brozek, C. M. et al. (J Clin Lab Immunol. 31(3): 105-9, March 1990), U.S. Patent Application Publication number 2002/0094542 A1 (effective filing date May 3, 1999), Rybak et al. (Proc. Nat. Acad. Sci. USA 89: 3165-3169, April 1992) and Halliwell (J. Am. Vet. Med. Assoc. 181(10): 1088-96, Nov. 15, 1982). The teachings of publication '8041 have been presented in the 102(e) rejection. This publication does not teach the method wherein the therapeutic composition further comprises an anti-CD74, cytokine, drug or toxin and the antibody component comprises a hapten with an attached therapeutic agent, as well as the treated B-cell disorders are autoimmune diseases selected from the group consisting of immune-mediated autoimmune hemolytic anemia, rheumatoid arthritis, systemic lupus erythematosus, bullous pemphigoid, pemphigus, and thrombocytopenia.

However, U.S. Patent Application Publication number 2002/0094542 A1 teaches the claimed method, wherein a therapeutic composition comprising conjugates composed of antibodies, cytotoxins and cytokines capable of binding more than one antigen for the treatment of cancer, as well as autoimmune diseases, see page 3, sections 0032 and 0046; page 9, section 0131; and page 14, section 0191. The therapeutic agents can be conjugated with haptenic groups, see page 12, section 0165; page 16, section 0213; and page 18, section 0243. Brozek teaches that anti-MHC class

II antibodies have been used to treat autoimmune diseases and that autoantibodies that bind HLA-DR inhibit rheumatoid factor production in peripheral blood mononuclear cells from rheumatoid arthritis patients. Rybak teaches the use of chimeric antibodies linked to toxins such as RNase to target tumor cells, see page 3165, abstract and introduction. Halliwell teaches autoimmune diseases of domestic animals, see entire document. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the different combinations of the therapeutic compositions for treatment of B-cell lymphomas and leukemias, including autoimmune diseases in domestic animals. It would have been *prima facie* obvious to add to the composition an additional antibody such as an anti-HLA-DR and a RNase toxin because Brozek teaches that anti-MHC class II antibodies are useful in the treatment of autoimmune diseases and publication '041 teaches a combination of antibodies for effective treatment and the cytotoxic potential of the RNase toxin is increased and functional experiments have proven tumor growth inhibitory activity. One of ordinary skill in the art would have been motivated to manufacture such a medicament in order to effectively treat companion animals/domestic animals because all publications set forth treatment of B cell malignancies targeting the cancer antigens, see all documents in their entireties.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
23 April 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643